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*Note: Text has been edited for clarity.*

**Contents:**                      **Transcript**

## **COVID-19 Pandemic Response Resources and FAQs for Animal Care and Use Programs**

*Speakers:*

- Pat Brown, VMD, NIH, Office of Laboratory Animal Welfare
- Robert Gibbens, DVM, USDA, APHIS, Animal Care

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Slide 1: COVID-19 Pandemic Response Resources and FAQs for Animal Care and Use Programs

>>*Neera:* Hello, everyone. Today is Wednesday, April 8, 2020. My name is Neera Gopee and I am the Director of [the Division of] Policy and Education at OLAW. Today it is my pleasure to welcome our speakers, Drs. Pat Brown and Robert Gibbens to present this special OLAW webinar titled: COVID-19 Pandemic Response Resources and FAQs for Animal Care and Use Programs.

Dr. Pat Brown currently serves as the Director, Office of Laboratory Animal Welfare (OLAW). She received her undergraduate degree in Animal Science from the Pennsylvania State University and her veterinary degree from the University of Pennsylvania. She completed her lab animal residency at Penn State Hershey Medical Center and is a diplomate of ACLAM. She served on active duty in the Air Force before joining the NIH in 1986 serving in several clinical and management positions in the Intramural Research Program before joining OLAW in 2006 as the Director.

Dr. Robert (Bob) Gibbens received his bachelor's degree in Zoology from Oklahoma State University in 1980. He received his Doctor of Veterinary Medicine degree from the Oklahoma State University College of Veterinary Medicine in 1984. He worked for 6+ years in a small animal practice in Oklahoma before becoming a Veterinary Medical Officer with USDA in 1990. He became a field supervisor with USDA, APHIS, Animal Care in 1995, and Regional Director of the Western Region in 1997. In 2016, he became the National Director of Animal Welfare Operations, and is currently acting as Animal Care's Associate Deputy Administrator. Dr. Gibbens is located in the Animal and Plant Health Inspection Service building in Ft. Collins, CO.

Before proceeding any further, we would like to take a moment to acknowledge that these are unprecedented times, and available information may change as the COVID situation unfolds. But rest assured, we will continue to be vigilant and are working diligently to monitor the situation as it evolves, develop necessary guidance, and connect with you and your institutions in any way we can to provide much needed information to ensure the health and well-being of personnel and animals in your programs. We have also developed many resources related to the COVID-19 pandemic, most of which we will introduce briefly in this webinar. Lastly, we will continue to

develop guidance, but in the meantime, please reach out to us if you have additional questions or concerns.

Now I'll hand the microphone over to Pat to get this discussion started.

Slide 2: NIH Grants and Funding webpage: Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding.

>> *Pat*: Hello. To get started, I'd like to highlight two resources where you can find an abundance of information related to the COVID-19 pandemic and its impact on research. The first is the [NIH Grants & Funding COVID-19 webpage](#) for NIH Applicants and Recipients of NIH Funding. I've included the webpage address at the bottom of this slide.

On this page you'll find frequently updated resources related to:

- Proposal Submission & Award Management
- Human Subjects & Clinical Trials
- Animal Welfare
- Peer Review
- Funding Opportunities Specific to COVID-19
- Resources like the CDC and WHO websites on COVID-19, and
- Frequently Asked Questions for each of these topics.

This page has been designed as a one-stop-shop for applicants and recipients of NIH funding, so if you have grant-related questions, this is a great place to start.

Slide 3: OLAW COVID-19 Pandemic Contingency Planning for Animal Care and Use Programs website

More directly related to our topic today, OLAW has just launched our new [COVID-19 landing page](#). You can navigate to this page simply by going to our home page, [olaw.nih.gov](http://olaw.nih.gov), and clicking on the red COVID-19 banner. I've also provided the webpage address at the bottom of the page.

We'll briefly highlight the resources available on this page, but it's important to note that this is different from our [Disaster Planning and Responses Resources](#) webpage.

The new webpage, that has been developed specifically for COVID-19, will be updated immediately as soon as additional guidance is developed. On this webpage, you'll find:

- OLAW-specific FAQs
- Guide Notices
- Webinars
- Example Disaster Plans
- Strategies to Optimize the Supply of PPE and Equipment
- Useful Links, and
- Contact information for OLAW for when you have additional questions.

Slide 4: Guide Notices

Before jumping into the FAQs, I quickly want to go through the other resources that are available, a little bit more in depth. As a reminder, OLAW provides guidance and advice in the form of Notices in the NIH Guide for Grants and Contracts, Frequently Asked Questions, published articles, and commentary in the Nature publication Lab Animal. This guidance represents the current thinking of OLAW. You may use an alternative approach to this guidance if it satisfies the requirements of the PHS Policy. To discuss an alternative approach, please contact us.

The first type of resource is Guide Notices. We have three Guide Notices on the website right now, and again, as additional guidance is developed, we will add it to this webpage.

Our most recent Guide Notice is [NOT-OD-20-088](#). This Notice highlights flexibilities for conducting semiannual facility inspections and IACUC meetings under the current pandemic situation.

Next, [NOT-OD-09-035](#) highlights flexibilities in using designated member review (also known as DMR), which may ease logistical constraints under the current pandemic situation.

Lastly is [NOT-OD-06-052](#), which highlights flexibilities in IACUCs using telecommunications for business requiring a quorum.

#### Slide 5: OLAW Webinars

We've also listed two webinars here; both were developed and broadcast within the last month.

In [Pandemic Contingency Planning and Its Impact on Animal Care](#), which was broadcast on March 19, 2020, Dr. Gibbens and I discussed how your institution can prepare for a pandemic that may impact your animal care and use program. Of note here is that we received many questions prior to the webinar. Although we were unable to answer many, we also amended the transcript with answers to additional questions. You can find that transcript on the webinar website, which I've linked here.

Next, in [Building a Research Occupational Health Program](#) that was broadcast on March 12, 2020, OLAW responded to questions relating to the COVID-19 pandemic in both the beginning and the end of the webinar. Again, the transcript is going to be a useful place for you to scan these questions.

#### Slide 6: Other Resources

We've also pulled together resources from institutions and other governmental agencies which may be helpful during the pandemic.

First, we have three great examples of disaster plans including the:

- NIH Division of Veterinary Resources Continuity of Services Plan
- Johns Hopkins University Animal Research Coronavirus Phased Contingency Plan, and the
- NIH 2008 Pandemic Flu Readiness Plan for Research Animals.

We'd like to thank our colleagues at both NIH and Johns Hopkins University for sharing these detailed plans with us.

Second, we've also posted three resources from the CDC on Strategies to Optimize the Supply of PPE and Equipment. These links cover a PPE Burn Rate Calculator, and other strategies for optimizing use of:

- Eye protection
- Isolation gowns
- Facemasks, and
- N95 respirators.

Third, we have Useful Links including links to COVID-19 webpages by such agencies as NIH, CDC, and the World Health Organization, and organizations like the American Veterinary Medical Association, the Environmental Protection Agency, and the U.S. Department of Agriculture.

#### Slide 7: USDA, APHIS, Animal Care

>> *Neera*: Thank you, Pat. Before we move on to the FAQs, which both OLAW and USDA will be addressing, our USDA colleague will provide an update on inspections, contact information, and essential personnel. Bob?

#### Slide 8: Facility Status and inspections

>> *Bob*: Thank you, Neera. Animal Care is continuing to conduct inspections when we become aware of serious animal welfare concerns, and the inspection can be conducted while maintaining appropriate social distancing. We are limiting those inspections based on our assessment of the risk to the inspectors and facility personnel. In the event that we do need to conduct an inspection, we understand that you may have exposure concerns or be dealing with very limited staff. Our inspectors will work with you to address those specific concerns, or we may use videos or photos, or simply come back another time. This will not be considered a refusal to allow inspection but rather a joint effort to address this serious public health emergency while still assuring the welfare of animals. As always, animals covered under the Animal Welfare Act should continue to receive appropriate care to ensure their health and well-being, and we are available to discuss individual situations with facilities.

#### Slide 9: Semiannual Program Review and Facility Inspections

We continue to get a lot of questions about semiannual program review and facility inspections. For USDA, facilities may delay semiannuals as long as necessary based on COVID-19 concerns. At this point, we're not placing a specific date on recommencing semiannuals in accordance with the regulations, because we don't know how long COVID-19 is going to impact your facilities' operations. Approval or permission is not needed from USDA to delay your semiannuals, but the delay should be documented so that our VMOs, during their next inspections, can verify what took place. And again, if a facility has specific concerns, we will work with that facility on an individual basis. Once semiannuals restart post COVID-19, the subsequent semiannuals should be six months after that date.

#### Slide 10: Facilities that also have Licenses

We do have a number of facilities, that in addition to their research registration also have an A or a B license to sell animals. I want you to know right now we have limited [access] to mail, so if you have an A or a B license and it's due for renewal during the pandemic, please contact us at the email address or telephone number on this slide [[animalcare@usda.gov](mailto:animalcare@usda.gov) or 970-494-7478]. Our office staff will walk you through the renewal process we are using during the pandemic. This would be the same for research facilities that wish to apply for a new A or B license during this time. Also, if your registration is due for its three-year update during the pandemic, you can complete the update by contacting the email address or telephone number on this slide.

#### Slide 11: Essential Employees

We've received multiple requests to identify for states or localities which employees at regulated facilities should be considered "essential." To address those requests, we have posted a stakeholder message on our website. The [link](#) is at the bottom of this slide. I do want to read the last paragraph, which is also copied on this slide. It reads:

"We know that facility employees are key to ensuring that appropriate care is provided to animals every day. State and local exceptions to travel and other restrictions are often focused on medical and emergency response personnel and may not include those employees who are so essential to the well-being of your animals. Animal Care cannot identify those essential personnel for each facility, but we encourage you each to do so. And while we cannot overrule local restrictions on

public citizens, we are available to explain the critical nature of the work of these essential employees to State or local officials if needed.”

#### Slide 12: Contacting AC

At this point, all of our office employees are now teleworking. We are all available. It is not known at this point how long teleworking will be necessary. And after this week, we will not be processing mail. So please communicate with us by email or telephone. If you send us something by mail, we will receive it when our offices open up after the pandemic.

You can still contact anyone in Animal Care, but the best contacts are on this slide. And again, you can reach us best by email or telephone.

#### Slide 13: USDA COVID-19 Landing Page

This is the [USDA's landing page](#) on the internet, which OLAW has also now posted a link to on its COVID-19 webpage. All updates concerning USDA operations and functions will be posted on this page. Please note that the updates will not likely be specific to the Animal Welfare Act, so when you have questions specific to the Act, and you cannot find what you are looking for on the USDA website, please use the contact information on the previous slide to get in touch with us.

And now, I'll turn it back over to Neera.

#### Slide 14: Frequently Asked Questions: Disaster Planning

>> *Neera*: Thank you, Bob. Now we'll move on to highly anticipated FAQs. The first category of questions addresses disaster planning.

#### Slide 15: **Do awardee institutions need animal facility disaster plans?**

Our first question asks: Do awardee institutions need animal facility disaster plans? Pat?

>> *Pat*: Yes. The *Guide* requires that institutions develop disaster plans that take into account the well-being of animals and personnel during unexpected events. The *Guide*, [page 35](#), states that the disaster plan “should define the actions necessary to prevent animal pain, distress, and deaths.” A comprehensive plan should include all the elements shown on this slide. Some of these topics are particularly relevant to pandemic planning such as:

- Plans for relocation of animals
- Provision of food, water, sanitation, and bedding during the disaster period
- Provision of services during significant personnel absences
- Establishment of institutional policies and procedures, including for when euthanasia is indicated
- Approval of the plan as a part of the overall institutional plan and integration with the local and state plans
- Identification of emergency responders and designation of responsibilities for when normal staffing is not possible
- Lastly, personnel training and practice in how to respond when different disasters occur.

Not only is a plan mandatory but periodic review and update of the plan is essential to adapt to program changes, evolving risks, and lessons learned from drills and actual disasters. In the current circumstance, IACUCs and animal programs should consider it as an opportunity to review their pandemic plan as part of semiannual program review, identify what worked and what didn't, and modify the plan to mitigate the problems that arose.

>> *Neera*: Bob, is there anything that you would like to add?

>> *Bob*: Yes, I wanted to make sure that everyone is aware that the USDA's contingency planning regulation which was stayed several years ago is still stayed. The USDA strongly encourages contingency planning, but it is not currently a regulatory requirement for research facilities.

Slide 16: **How can institutions and their IACUCs best prepare for a pandemic [like COVID-19]?**

>> *Neera*: Our second question related to disaster planning is: How can institutions and their IACUCs best prepare for a pandemic [like COVID-19]?

>> *Pat*: The best way to prepare for a pandemic is to have a strong plan in place, with well-trained personnel who are ready to put the plan into action at a moment's notice. When developing the plan, visit our [COVID-19 webpage](#) and our [Disaster Planning and Response Resources](#) webpage to find resources for developing plans to prepare for and respond to disasters and public health emergencies. During a pandemic, institutions must still adhere to provisions of the PHS Policy and the *Guide*. This includes advance planning for conditions that could arise as a result of a pandemic that may jeopardize the health and well-being of animals because of a lack of personnel to provide care for the animals and personnel to conduct IACUC official business.

Pandemic plans developed by institutions and IACUCs should consider the following, in addition to what we discussed in the last slide.

The IACUC should develop a plan for conducting official business during a pandemic event, taking into account the following:

- The IACUC must continue to be properly constituted
- A quorum is required to conduct official business at a convened meeting
- The IACUC must ensure that protocol approvals are not allowed to expire or if they do expire, that no further animal activities are conducted
- Appointment and training of IACUC members (including nonscientific members and alternates) should be considered as a part of the plan [see [NOT-OD-11-053](#)].

In devising a pandemic plan, the institution may wish to consider using options provided in the PHS Policy that it does not choose to use in the normal operation of its animal care and use program. The PHS Policy allows for physical distancing measures to reduce contact among people to prevent the spread of disease, including:

- Expanded use of designated member review in lieu of full committee review
- Using alternatives to face-to-face meetings such as teleconference or video conferencing
- Reducing the number of meetings to as few as one every six months, the minimum allowed by the *Guide*.

Slide 17: Frequently Asked Questions: Animal Care

>> *Neera*: The next category of FAQs is related to the topic of animal care.

Slide 18: **If animals already on study were schedule for post-op analgesia or other required treatment for clinical care, but the institution shuts down before the treatments are given, is this considered protocol noncompliance to OLAW and USDA?**

The first FAQ under this topic asks: If animals already on study were scheduled for post-op analgesia or other required treatment for clinical care, but the institution shuts down before the treatments are given, is this considered protocol noncompliance? Pat?

>> *Pat*: Remember, our primary concern during the pandemic is the health and well-being of personnel and animals. Not providing the required post-op analgesia or other required treatments for clinical care as described in the approved animal study protocol may be considered a reportable noncompliance because adequate veterinary care was not provided. The circumstances surrounding the incident should be discussed with the OLAW Division of Compliance Oversight before reporting.

The *Guide* requires that "Procedures must be in place to provide for emergency veterinary care both during and outside of regularly scheduled hours." This includes instances where the institution is not operating under a normal schedule. If appropriate animal care cannot be provided, subsequent procedures requiring post-op analgesia should not be initiated.

>> *Neera*: And Bob, is there anything else USDA would like to add to this?

>> *Bob*: We agree with OLAW with regard to ensuring the health and well-being of personnel and animals. And with the USDA, we would consider the failure to provide post-op analgesia a noncompliance with the requirement to provide adequate veterinary care.

**Slide 19: If animals already on study need to be euthanized because the institution has shut down, what type of documentation or reporting is expected of the IACUC for USDA and OLAW?**

>> *Neera*: Thank you. Here's our second FAQ regarding animal care: If animals already on study need to be euthanized because the institution has shut down, what type of documentation or reporting is expected of the IACUC? Bob?

>> *Bob*: Euthanasia should be a last resort. And the decision to euthanize animals must involve the Attending Veterinarian. If the Attending Veterinarian agrees it's appropriate to euthanize the animals, then the animals should be euthanized in a manner that meets the definition of euthanasia in the regulations of the Animal Welfare Act. As far as documentation for USDA, that would depend upon the species. For cats and dogs, disposition documentation is required.

>> *Neera*: Pat, what's OLAW's position on this topic?

>> *Pat*: OLAW agrees with USDA that euthanasia of animals should be a last resort and the circumstances for when it is necessary should be described in the institution's disaster plan. It is an institutional decision involving the veterinarian and the institution's leadership. Careful planning and alternatives to consider include:

- Transferring animals to a holding protocol
- Postponing unnecessary procedures or manipulations
- Relocating animals to another facility, and
- Cryopreservation for certain species.

**Slide 20: If animals are currently in the vivarium but experiments have not started yet, can the animals be kept temporarily on a holding protocol (per diem charges still to the grant) until animals are used at the later postponed date?**

>> *Neera*: Here is another FAQ on animal care: If animals are currently in the vivarium, but experiments have not yet started, can the animals be kept temporarily on a holding protocol and can per diem rates be charged to the grant until animals are used at the later postponed date? Pat?

>> *Pat*: Yes. Animals may be placed on an IACUC-approved holding protocol and maintained throughout the duration of the research stoppage. [Updated 07/22/2020: Please see the NIH

Guide Notice, ~~NOT OD 20 086~~ linked here for NIH grants policy guidance on rebudgeting authority. This notice describes several flexibilities available to NIH grant recipients affected by COVID-19. Recipients may rebudget funds to accommodate unanticipated costs without prior approval when rebudgeting does not constitute a change in scope and is not restricted by the terms and conditions of award (see [NIH GPS 8.1](#)).]

And OLAW would, in fact, much rather that you take this step rather than euthanize animals.

**Slide 21: If investigators halt animal work due to the pandemic, preventing congruency with the approved protocol timeline, what is required of the investigator or the IACUC? Is it acceptable to USDA and OLAW to issue a blanket statement allowing investigators to alter timelines, rather than requiring each PI to amend their study?**

>> *Neera*: Another FAQ related to the topic of animal care asks: If investigators halt animal work due to the pandemic, thereby preventing congruency with the approved protocol timeline, what is required of the investigator or the IACUC? Is it acceptable to issue a blanket statement allowing investigators to alter timelines, rather than requiring each PI to amend their study? Bob?

>> *Bob*: A blanket statement would be a satisfactory mechanism to document the delay in research activities. If the delay extends beyond the time for the required “not less than annual” protocol review, that should be documented, and that annual review should be conducted when the activity restarts. How those animals would be reported on the facility’s annual report will depend upon the circumstances. And we will put out guidance about this when we send out the annual report packets towards the end of the fiscal year.

>> *Neera*: And Pat?

>> *Pat*: When non-essential research is halted during this time, it contributes to the greater cause by allowing critical duties such as maintaining daily animal care to take priority. The IACUC may identify the impacted protocols and transfer them *en masse* to holding protocols with the expectation that the research protocols may require modifications when facilities become operational. Basically, the IACUC may take advantage of the use of holding protocols, but should document the action, as each protocol may eventually need to be modified. This would be considered a program change that the IACUC should agree to and may be accomplished as part of semiannual program review.

**Slide 22: Can OLAW and USDA discuss what options are available for institutions that are “shut down” and their animals must be relocated because their facility is being taken over for other functions related to COVID-19?**

>> *Neera*: So, here is the final FAQ on animal care: What options are available for institutions that are “shut down” and their animals must be relocated because their facility is being taken over for other functions related to COVID-19? Pat, would you like to take this one?

>> *Pat*: If the decision is made to relocate animals because the facility will be used for other functions, here are some possible options to consider:

- Partner with a neighboring institution to place the animals within the neighboring institution’s animal program.
- Move animals to another building within the institution, being mindful of environmental conditions and the need for continuing care. OLAW does not recommend taking the animals to an individual’s residence due to concerns for both human and animal health.
- For critical strains of mice, consider cryopreservation. Several commercial institutions have expertise in cryopreserving and maintaining critical strains.



- Depopulation or euthanasia should be a last resort. The circumstances for when it is necessary should be described in the disaster plan, and the institution's leadership and veterinarian should be involved in the decision to proceed.

As always, for guidance on specific situations, call or email OLAW and we will be happy to help.

>> *Neera*: Bob, is there anything you'd like to add to this?

>> *Bob*: Yes, if facilities need assistance relocating animals during the pandemic, I encourage you to let us know. Depending upon the species, we may be able to recommend available facilities. Also, during the pandemic, it is not required to have a new location that is going to temporarily house your covered animals inspected before the animals are moved there; but it is required to house them in conditions that meet or exceed the requirements of the Animal Welfare Act.

Slide 23: Frequently Asked Questions: IACUC Functions

>>*Neera*: Thank you. Our last category of FAQs is specific to IACUC functions.

Slide 24: **What are these waivers we're hearing so much about?**

Pat, OLAW has the authority to review and approve or disapprove waivers to the PHS Policy. Before we dive in any further, can you give us a broad overview regarding waivers to the PHS Policy and when would these waivers be applicable during the COVID pandemic?

>> *Pat*: Certainly. So, there are three documents that govern animal care and use programs of Assured institutions. The first is the PHS Policy, that includes the requirement for an Animal Welfare Assurance with OLAW, which is the second document, and then there's the *Guide for the Care and Use of Laboratory Animals* (the *Guide*).

The waivers are related to the PHS Policy *only*, because that's where the waiver authority originates. Section V.A.5. gives OLAW the authority to approve or disapprove waivers to the Policy, and [Section V.D.](#) states that institutions may request them. OLAW may temporarily waive specific IACUC functions when institutions request a waiver by submitting a request with justification to OLAW. The Policy requires the waiver to be reviewed and approved in writing by OLAW.

Slide 25: **Functions of the IACUC**

>> *Neera*: Pat, you mentioned in the previous slide that OLAW can waive specific IACUC functions as described in the PHS Policy. Can you expand on some of these IACUC functions?

>> *Pat*: Certainly. Here are just some of the IACUC functions described in the PHS Policy, but we're not going to be issuing waivers for all of them at this time, and that's primarily because so many of them can be conducted virtually. So, examples of IACUC functions include:

- Semiannual program review
- Semiannual facility inspections
- IACUC reports
- Protocol review, and
- Reporting requirements (this would include noncompliance reporting—noncompliance with the PHS Policy, serious deviations from the *Guide*, and protocol suspensions).

The one IACUC function that we're issuing waivers for currently is the semiannual facility inspections, because the others can be done virtually or through other mechanisms. I will discuss some of these other mechanisms later in the presentation.

**Slide 26: What option is available if institutions cannot adhere to provisions of the PHS Policy due to the impact of COVID-19?**

>> *Neera*: So now that we know more about what IACUC functions are in the PHS Policy, what options are available if institutions cannot adhere to provisions of the PHS Policy due to the impact of COVID-19?

>> *Pat*: OLAW may temporarily waive specific IACUC functions in accordance with PHS Policy [Section V.D.](#) The authorized institutional representatives (including Institutional Officials, IACUC Chairs, IACUC Coordinators, and Attending Veterinarians) may request a waiver by submitting a request with justification to OLAW at [olawdpe@mail.nih.gov](mailto:olawdpe@mail.nih.gov). The waiver will be reviewed and approved in writing by OLAW, and then sent back to the institution via email. As already mentioned, OLAW is the only entity authorized to make determinations regarding waivers to provisions of the PHS Policy.

As I mentioned in the previous slide, OLAW is currently issuing waivers for the semiannual facility inspections, because the other IACUC functions can be done virtually or through other mechanisms.

**Slide 27: What option is available if institutions cannot adhere to provisions of their Assurance due to the impact of COVID-19?**

>> *Neera*: What option is available if institutions cannot adhere to the commitments detailed in their Animal Welfare Assurance with OLAW due to the impact of COVID-19?

>> *Pat*: Well it's important to remember how these pieces all fit together. The PHS Policy is intentionally vague, in that it states requirements, but not how these requirements need to be met. That's where your institution's Assurance comes in. The Assurance is the document that spells out how your institution is going to meet the requirements of the PHS Policy in a way that works best for your institution. And it isn't a static document, unlike the PHS Policy. Your institution can update OLAW on changes made in the annual report, and every four years when the Assurance is renewed.

An example of an institution-specific standard procedure that doesn't need to be communicated to OLAW right away, and does not need a waiver, is if semiannual program review usually occurs at an extended IACUC face-to-face meeting in May and then due to COVID-19, it will take place with a subcommittee and be conducted virtually in May or June. The six month plus 30 days allowance applies to program review as well as facility inspections.

In this example, the institution is conducting a semiannual program review, as required by the PHS Policy, Section IV.B.1., that says the IACUC shall... "review at least once every six months the institution's program...using the *Guide* as a basis for evaluation." The Policy also describes requirements for reporting to the IO, but it does not state the duration of the review or whether it will be conducted in person. Again, the commitments in your Assurance are how you make the PHS Policy work for you and may be changed as needed using your annual report or when renewed.

So again, as long as you're complying with the elements of the PHS Policy, [using] the flexibilities that it offers, a waiver is not required. If you are doing something other than what's described in your Assurance because of COVID19, update OLAW if it becomes part of your permanent program.

**Slide 28: What option is available if institutions cannot adhere to provisions of the *Guide* due to the impact of COVID-19?**

>> *Neera*: Thank you, Pat. And, so can you tell us now what option is available if institutions cannot adhere to provisions of the *Guide* due to the impact of COVID-19?

>> *Pat*: So, nothing has changed from the normal circumstances regarding deviations from the *Guide*. So, this is a [flow chart](#) you can find on the OLAW webpage that describes the three types of statements in the *Guide* (must, should, and may), and when they need to be reported to either the Institutional Official or OLAW.

A good example under the current circumstances would be when the IACUC is asked to approve extended caging and equipment sanitizing schedules outside *Guide* recommendations and outside the facility's normal performance standards. The *Guide* on page 70 states that enclosures and accessories should be sanitized at least every 2 weeks. The changes requested are based on veterinary recommendations to manage the animal facility during reduced staffing. So, this would be an IACUC reviewed and approved departure and it should be included in the semiannual report to the IO. Because of the inherent flexibility in the *Guide* and the PHS Policy, the IACUC may approve *Guide* departures that arise during a pandemic or other disaster and include the change in the next semiannual report to the IO, and there's no requirement to request a waiver or inform OLAW of this kind of activity.

**Slide 29: Are there flexibilities available to IACUCs regarding the conduct of IACUC meetings and semiannual inspections?**

>> *Neera*: The next section is very important, so we'll be going through this in small increments. It addresses the flexibilities available for the conduct of IACUC meetings and semiannual inspections under the current pandemic situation.

So, my first question to you Pat, is: Are there flexibilities available to IACUCs regarding the conduct of IACUC meetings and semiannual inspections?

>> *Pat*: Well, as many of you probably know by now, we released a Guide Notice on Flexibilities for Assured Institutions for Activities of IACUCs due to COVID-19, NOT-OD-20-088. This Guide Notice covers flexibilities of the PHS Policy for IACUC meetings and semiannual inspections. We will be going over this in much more detail in the next few slides.

The purpose of the Guide Notice was to empower institutions to implement changes to the conduct of their semiannual facility inspections and IACUC meetings using the flexibilities that already exist in the PHS Policy and are meant to facilitate physical distancing.

**Slide 30: Do institutions need a waiver to implement the flexibilities in OLAW's NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business? Does USDA concur?**

>> *Neera*: Thank you, Pat. A follow-up question asks: Do institutions need a waiver to implement the flexibilities in OLAW's NOT-OD-20-088 regarding the conduct of semiannual inspections and IACUC business? But Pat, first I'd like to just focus on semiannual inspections, and then we'll address the IACUC business later on in this webinar.

>> *Pat*: Certainly. This question seems to be causing some confusion for our community, so we're going to spend a few slides on this.

In the last slide, we covered that there *are* flexibilities for semiannual inspections and IACUC business. Now, let's talk about what those are—and again, these are flexibilities that your institution can implement at any time, given the rules in the last slide; that is, keeping the IACUC informed, and providing updates in your annual report and Assurance when it is renewed, if these become continuing activities of your IACUC.

First, the Notice covers conduct of semiannual facility inspections. Well, there are several flexibilities here:

- The first is that the timing of facility inspections may extend 30 days beyond the six-month interval from the last review if there is no forward drift of the date from year to year. This would also be applicable if you're using the AAALAC site visit as a substitute for the facility inspection.
- The second is that the IACUC has discretion to determine the best means of conducting the facility inspections. This includes using any qualified individual as an ad hoc consultant. For areas housing non-USDA regulated species, the IACUC may use as few as one qualified individual to conduct the inspections. The IACUC still remains responsible for the evaluation and the report to the Institutional Official. Again, the use of a recent AAALAC site visit would qualify as long as the IACUC accepts the recommendations from the site visit team, develops a corrective action plan for each recommendation, and incorporates both the recommendations and corrective action plans in their semiannual report to the IO.

Lastly, we'll cover this again later, but you can use ad hoc consultants (again, someone qualified, like a facilities manager, for example) to conduct virtual tours and broadcast those to other IACUC members.

>> *Neera*: And Bob, does USDA concur with OLAW's position?

>>*Bob*: Yes, and as mentioned earlier, for USDA, semiannual inspections can be delayed as long as necessary based on COVID-19 impacts. No approval or permission is needed from the USDA, but the delay should be documented. And, if you are conducting semiannual inspections, and as Pat already mentioned, there are several flexibilities available to you, and these are the same for USDA. These include:

- The use of ad hoc consultants
- Live video streaming
- Use of a recent AAALAC site visit, and
- IACUC members that are conducting the inspection do not have to inspect the same areas. They can each inspect different areas individually.

Slide 31: **Do institutions need a waiver to implement the flexibilities in OLAW's NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business?**

>> *Neera*: Pat, would you like to discuss this slide?

>>*Pat*: Yes, so the only reason that you would need a waiver for facility inspections was if you could not complete the inspection as described in the first bullet, within six months and 30 days of the last inspection.

So, the question you really need to ask to determine whether or not you need to request a waiver to implement the flexibilities in our Guide Notice is: Will you be able to safely conduct your semiannual facility inspections within six months and 30 days of your last semiannual inspection? If the answer is yes, there is no need to notify OLAW or request a waiver since this timeframe is compliant with OLAW's guidance. However, if you are unable to conduct facility inspections within this six-month plus 30-day timeframe because of the COVID-19 pandemic, you may request a waiver from OLAW. You don't have to make this decision right now—we'll be issuing waivers on a rolling basis as long as necessary.

>> *Neera*: Bob, is there anything you'd like to emphasize here again?

>> *Bob*: Sure. Just to reiterate one more time, you do not need approval or permission from the USDA to delay your semiannual inspection, just document the delay.

Slide 32: **What happens if you do request (and are approved for) a waiver to semiannual inspections?**

>> *Pat*: Now, let's look at what happens if you request and are approved for a waiver to semiannual inspections. I will go over how to request a waiver in just a minute.

So, let's say your IACUC has regularly scheduled semiannual inspections on October and April 1<sup>st</sup> of each year, and you were able to complete your semiannual inspections on time last fall. But for the April 1<sup>st</sup>, 2020, inspection, your institution was shut down, and it remained shut down through May 20, which is past the 30-day grace period where you don't need a waiver.

So now you're in waiver territory.

You must complete the semiannual inspections as soon as it is safe to do so. It might not be the same day your institution reopens, but soon after, we would expect you to start inspections and taking stock of the situation. So, let's say that happens on May 22.

Your first option is to get back on the schedule of your semiannual inspections, and conduct them again on October 1, which would lead you to have about a four-month inspection interval.

The other option is for you to delay your inspection to a new six-month interval. So if you conducted your post-COVID-19 semiannual inspection on May 22, the next semiannual inspection could be on November 22 and no later than December 22 (if you're implementing the six month plus 30 day flexibility) and as long as there is no continued forward drift from year to year in the future.

Note that it would *not* be acceptable to skip the interim semiannual inspection altogether and start again October 1.

Slide 33: **Do institutions need a waiver to implement the flexibilities in OLAW's NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business? Does USDA concur?**

Now let's return to the question at hand and talk about flexibilities for IACUC business. And again, to implement these flexibilities, just like I talked about before, you must ensure that all IACUC members are kept apprised of the flexibilities prior to implementation, and that any permanent program changes are included in the 2020 annual report to OLAW. The Assurance should then be updated at the time of renewal if these become part of the institution's ongoing plan.

For IACUC meetings, three flexibilities include:

- The ability to conduct virtual meetings

- Reducing the number of meetings to as few as one meeting every six months, as required by the *Guide*, and
- The expanded use of designated member review vs. full committee review.

These are also flexibilities that are always available, they are not COVID-19 specific flexibilities, and thus there is no need to request a waiver.

>> *Neera*: And Bob, what is USDA's position on this topic?

>>*Bob*: USDA encourages the use of the same flexibilities, such as:

- Conducting virtual meetings (and this is described in chapter seven of our Inspection Guide)
- The expanded use of designated member review, and
- Reducing the number of IACUC meetings to as few as is required by the regulations.

**Slide 34: How may the IACUC extend a protocol that is due to expire and still meet the PHS Policy requirements?**

>> *Neera*: Thank you. So, here's another question related to IACUC business, Pat: How may the IACUC extend a protocol that is due to expire while still meeting the PHS Policy requirements?

>> *Pat*: The IACUC may extend the three-year approval by IACUC review using the procedures in PHS Policy IV.C.2, for designated member review (DMR). An example of how to expedite the continuing three-year review of the current protocol using DMR includes the following steps:

- Due to the pandemic or other disaster, the IACUC establishes a shortened response time for calling for full committee review that is agreed to by the members, for example two business days.
- The IACUC also agrees to a policy with a standard period to extend the protocols due to expire, for example six months.
- All IACUC members receive a list of research protocols due to expire and access to the necessary information on the protocols to be reviewed.
- If any member asks for certain protocols to go before the full committee, then the indicated protocols must be deferred for full committee review [FCR]. Any member may ask to send the protocol to FCR at any time during the agreed time period.
- If no member calls for full committee review, the Chair refers the protocols to a designated reviewer. The Chair may select one or more members, qualified to review the protocols, who act on behalf of the entire IACUC to either approve the protocols, request additional information from the PI to approve them, or refer for full committee review.
- Once approved, the protocols are extended based on the IACUC's policy, in this case six months.
- Only the procedures described in the protocol approved by the designated member may be performed unless a subsequent amendment is submitted and reviewed and approved.

The designated reviewer approval has equal validity to full committee review approval and does not require subsequent reapproval or notification by a convened meeting. It is always possible for the IACUC to discuss protocols approved by either method in future meetings as a form of continuing review or in response to animal welfare concerns.

Slide 35: **Do institutions need a waiver to implement the flexibilities in OLAW's NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business?**

Bringing this all back together. Before requesting a waiver, ask yourself whether your IACUC will be able to safely conduct the semiannual facility inspection within six months and 30 days of the last inspection. If the answer is yes—there is no need to request a waiver. If the answer is no—go ahead and request a waiver.

The other flexibilities that we have discussed do not require a waiver—just keep the IACUC informed, and if using these flexibilities as a permanent part of the IACUC's program of oversight, provide the changes in your institution's annual report and Assurance when it is renewed. For example, if the IACUC begins using designated member review when it had exclusively used full committee review for review of new protocols and decides to continue to use designated member review once the pandemic has passed, this would be a change to include in the annual report and when the Assurance is renewed.

Slide 36: **How can institutions request waivers if the IACUC cannot safely complete the semiannual facility inspections 30 days beyond the six-month interval from the last facility inspection?**

>> *Neera*: Pat: How can institutions request waivers if the IACUC cannot safely complete the semiannual facility inspections 30 days beyond the six-month interval from the last facility inspection?

>> *Pat*: As previously presented, the authorized institutional representatives, such as Institutional Officials, IACUC Chairs, IACUC Coordinators, and Attending Veterinarians, may request a waiver by submitting a request with justification to OLAW at [olawdpe@mail.nih.gov](mailto:olawdpe@mail.nih.gov).

The waiver will be reviewed and approved in writing by OLAW, and then sent back to the institution via email.

As already mentioned, OLAW is the only entity authorized to make determinations regarding waivers to provisions of the PHS Policy.

Slide 37: **For USDA and OLAW, can one person broadcast virtual tours to other IACUC members as part of the semiannual facility inspections?**

>> *Neera*: Speaking of semiannual inspections and flexibilities: For both USDA and OLAW, can one member broadcast virtual tours to other IACUC members as part of the semiannual facility inspection? Bob?

>> *Bob*: Yes, a live video feed can be used for your semiannual inspection as long as the following provisions are met:

- First, the video feed must be live, so that IACUC members watching the video feed can direct the camera to focus on specific areas.
- Also, at least two committee members must be involved with either filming or reviewing the video feed, and
- No committee member wishing to participate can be excluded.

>> *Neera*: And would this be acceptable to OLAW, Pat?

>> *Pat*: Yes, this is a great way to facilitate physical distancing while overseeing your animal care and use program with minimal disturbance.

The PHS Policy affords flexibility in that “The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution’s programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation.” However, as we’ve said before, the IACUC remains responsible for the evaluation and report.

So, yes, one person that the IACUC considers qualified may broadcast the virtual tour to other members. This also has the benefit that it allows real-time interaction during the inspection.

**Slide 38: Will OLAW approve waivers for the semiannual program review?**

>> *Neera*: So, in our next question, we’ll switch from semiannual inspections to semiannual program reviews. The question is: Will OLAW approve waivers for the semiannual program review?

>> *Pat*: Again, a waiver request will only be required if it is necessary to deviate from the PHS Policy. At this point, OLAW expects Assured institutions to explore and implement the available flexibilities when conducting the semiannual program review and also for protocol reviews and only request waivers for justifiable reasons. Semiannual program review and in particular, review of the institution’s disaster plan, is even more critical and necessary to ensure the health and safety of personnel and animals during the pandemic. The six month plus 30 day timeline is not only applicable to the semiannual facility inspections, but it also applies to the semiannual program review.

The PHS Policy affords flexibility in that “The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution’s programs. The IACUC may invite ad hoc consultants to assist in conducting the evaluation.” However, as I’ve said previously, “the IACUC remains responsible for the evaluation and report.” One option is for the semiannual program review to be conducted by using teleconferencing, or video conferencing.

Another example of program review using physical distancing is for IACUC members to be assigned various elements of the program to review using the [OLAW checklist](#), or the AAALAC program description, if the institution is AAALAC accredited. The members provide written reviews identifying changes in the program. The reviews are compiled and shared via email for the entire IACUC to consider. Members add any comments to the compiled report and the final version is signed via email with digital or scanned signatures. However, keep in mind the following:

- No IACUC member should be involuntarily excluded from participating in the program review.
- The majority of the IACUC must sign the resulting semiannual report to the IO. This may be handled via email with digital or scanned signatures.

Once the program review is completed, it must be submitted to the IO.

**Slide 39: Ex: Semiannual Program Review under COVID-19**

I’d just like to expand on this idea of semiannual program review under the COVID-19 pandemic a little bit more. And you can see this has been created on the slide to show you the various aspects of how this can be conducted.

So, let’s say you’re an institution with a seven person IACUC who are teleworking due to COVID-19, and you have a fairly large animal program, such that two of three veterinarians employed by the institution are teleworking on any given day to facilitate physical distancing. That would be Fred and Fran.



Using the OLAW Semiannual Program Review checklist and modifying it to be appropriate for your institution, there are 12 sections in the Institutional Policies and Responsibilities checklist and six sections in the Veterinary Care checklist of the program review.

The IACUC administrator or Chair can assign aspects of each checklist to one or several members of the committee based on qualifications, or members can volunteer for the section that they prefer to review. Again, ad hoc consultants could be assigned, as long as they're qualified. So, in this example, Dale (an occupational health and safety specialist who's not a member of the committee) could serve as an ad hoc consultant to the committee and assist Debbie in reviewing sections 10-12 of the IACUC's program using the OLAW Checklist.

Likewise, the veterinarians could each review three sections of the OLAW Veterinary Care checklist.

During this time, the other flexibilities previously mentioned may or may not be employed, including:

- Additional ad hoc consultants (like Dale helping Debbie)
- Virtual meetings between assigned members could also be effective
- Eventually the larger IACUC may choose to review and discuss virtually to finalize the checklist review that results then in the report to the IO.
- Another flexibility is for one designated member or an administrator to compile the changes into the final report and obtain at least a majority of the committee members concurrence via email with electronic signatures.

There are very many variations on this suggested example based on the existing flexibilities in the PHS Policy. OLAW encourages IACUCs to develop creative solutions that work best for the size of their program and if you have questions do not hesitate to contact us for guidance.

Slide 40: **Will OLAW and USDA waive quorum requirements in case the IACUC has to be convened to make decisions on short notice?**

>> *Neera*: Our next question is: Will quorum requirements be waived in case the IACUC has to be convened to make decisions on short notice? Bob?

>> *Bob*: Under the regulations of the Animal Welfare Act quorums are required when:

- Approving, withholding approval, or requiring modifications to proposed activities using full committee review, and
- When suspending a research activity.

This is not changing during the pandemic—quorum requirements are not going to be waived. But as both Pat and I have mentioned, the use of designated member review and virtual IACUC meetings are viable options available to you in lieu of face-to-face meetings.

>> *Neera*: Does OLAW concur, Pat?

>> *Pat*: [Yes] Quorum requirements will not be waived. Quorums are mandated by the PHS Policy for only two conditions:

- suspension of a protocol, and
- full committee review of protocols or significant changes.

But as we've already mentioned there are a number of flexibilities available which don't require a waiver from OLAW. For instance:

- The number of IACUC meetings may be reduced to as few as one every six months, as required by the *Guide*.
- IACUCs may meet virtually in accordance with our guidance on use of telecommunications, and
- IACUCs may also conduct official IACUC functions using designated member review.
- Don't forget also that if the IACUC has an approved policy, veterinary verification and consultation may be used for applicable significant changes to protocols.

Slide 41: **Will there be any flexibility for the three-year complete review?**

>> *Neera*: We've discussed the flexibilities for the semiannual program review, but will there be any flexibility for the three-year complete review, Pat?

>> *Pat*: No, protocols must be renewed prior to the three-year expiration date. This is something that can be done remotely, so IACUCs should consider using the flexibilities described in our Guide Notice that I have presented. The IACUC may use full committee review conducted virtually using electronic meeting formats or teleconferences in accordance with our telecommunications guidance.

Or, the three-year review may be conducted using designated member review. And, as I described in an example in slide 34, DMR may be used to extend the approval of a current protocol until after the pandemic's impacts have subsided.

>> *Neera*: And Bob, is there anything you'd like to add?

>> *Bob*: Just that under the Animal Welfare Act, there is not currently a requirement for a three-year complete review.

Slide 42: **USDA and OLAW, how can we continue to perform post approval monitoring activities when access to animals or animal housing areas are minimized or restricted due to COVID-19?**

>> *Neera*: Thank you. We're also receiving many inquiries regarding how to conduct or how to perform post approval monitoring activities when access to animals or animal housing areas are minimized or restricted due to COVID-19. Bob, what advice can you give?

>> *Bob*: Under the Animal Welfare Act regulations, the primary PAM activity is the continuing review of research activities not less than annually. And as I mentioned earlier, if a research activity is halted or delayed during the pandemic, and the "not less than annual review" is due during that time frame, the review should take place at the time the research activity recommences. And the delay should be documented so that our VMO can verify what took place during their next inspection.

>> *Neera*: And Pat?

>> *Pat*: The PHS Policy requires continuing IACUC oversight of animal activities, but it does not explicitly require specific post approval monitoring (PAM) procedures. Post approval monitoring may be accomplished through many different mechanisms which may include daily observation of animals by trained animal care personnel. There is no requirement that the formal post approval monitoring program described in the Animal Welfare Assurance continue, especially if there are reduced or limited research activities going on in the facility. If, as a result of the pandemic,

changes are made to the PAM program and it becomes part of the ongoing program of oversight, those changes should be described in the next annual report to OLAW and in the Assurance when renewed.

**Slide 43: Do institutions need to notify OLAW or request a waiver from OLAW if implementing the flexibilities described in Guide Notice NOT-OD-20-088 that are not currently described in their Animal Welfare Assurance?**

>> *Neera*: The next question is: Do institutions need to notify OLAW or request a waiver from OLAW if implementing the flexibilities described in our Guide Notice NOT-OD-20-088 that are not currently described in their Animal Welfare Assurance?

>> *Pat*: No, a waiver from OLAW is not required for institutions employing the flexibilities provided in the PHS Policy that are applicable to a pandemic situation. This includes provisions that may be instituted as physical distancing to prevent the spread of disease. However, institutions must ensure that all IACUC members are kept apprised of the flexibilities being employed prior to implementation and that any permanent program changes are included in the 2020 annual report to OLAW. The Assurance should then be updated at the time of renewal if these become part of the institution's ongoing plan.

>> *Neera*: Bob, is there anything you'd like to add?

>> *Bob*: Yes, let me emphasize this one more time that no waiver or approval is needed to delay your semiannual program reviews or inspections, or the "not less than annual" review of research activities. But those delays should be documented.

**Slide 44: Do we need to report institutional closures to OLAW or USDA?**

>> *Neera*: The next question asks: Do we need to report institutional closures to OLAW or USDA?

>> *Pat*: OLAW's current plan is that as institutions request a waiver for semiannual inspections, we are documenting the request. OLAW does not need to know about the closure itself if the institution is maintaining appropriate care for the animals during the closure. Any conditions that jeopardize the health or well-being of animals must be promptly reported to OLAW.

>> *Neera*: And Bob?

>> *Bob*: Like OLAW, USDA is not requiring research facilities to notify us of closures during the pandemic. The primary focus should continue to be the health and well-being of the animals.

**Slide 45: Can Assured institutions donate Personal Protective Equipment (PPE) and supplies acquired with NIH or USDA grant funds to local hospitals and health care facilities in support of COVID-19 efforts?**

>> *Neera*: We've also had an influx of requests from people wanting to step in and help during the pandemic. One way they're thinking of doing this is by donating Personal Protective Equipment (PPE) and supplies acquired with [NIH] grant funds to local hospitals and health care facilities in support of COVID-19 efforts? Is this allowable?

>> *Pat*: Yes, we've been heartened at the number of people who are looking for ways to help the relief efforts. [Updated 07/22/2020: ~~Assured institutions may donate unneeded or surplus PPE and other supplies in support of efforts related to COVID-19. Grantees may contact the NIH awarding Institute or Center to request administrative supplements to support repurchasing of these supplies at a later date. Please see NIH's Guide Notice, [Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19](#) for guidance on rebudgeting authority.~~ Recipients may request prior approval to donate PPE and other lab supplies to

hospitals, medical centers, and other local entities that are directly serving the public health emergency crisis for COVID-19 response. The guidance originally provided in OMB Memo [M-20-20](#) has ended, effective June 16, 2020. NIH will consider future requests on a case by case basis.]

>> Neera: Bob, does USDA have a position on this?

>>*Bob*: As far as the USDA is concerned, this is totally an institutional decision.

Slide 46: Summary

>>Neera: Thank you. This chart summarizes the key FAQs with respective responses from both OLAW and USDA that is sure to be useful for your animal care and use program during the COVID-19 pandemic. Please feel free to use it as an aid to your decision-making process during these uncertain times.

Slide 47: Summary, continued 1:

It addresses your semiannual program reviews, inspections, waivers...

Slide 48: Summary, continued 2:

...delay of three-year complete review, requirements for a quorum...

Slide 49: Summary, continued 3:

...euthanasia of animals, halting of protocols...

Slide 50: Summary, continued 4:

...and, closing of institutions.

Slide 51: OLAW Contacts

We've come to the end of this important discussion and hope that you find this webinar useful during these uncertain times. Again, OLAW's and USDA's immediate concern is for the health and safety of the people and animals in the programs we oversee. Many thanks to Pat and Bob for taking the time to provide pertinent resources and for responding to these FAQs in an effort to ensure institutional compliance and promote good animal welfare during these unprecedented times. Thank you for your continued understanding and patience as we navigate the emerging COVID-19 crisis. Be safe and be well. Goodbye.

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